

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1 and 2 are pending. In this response, claim 1 is amended for further clarity. Support for the amendment can be found in the specification and claims as originally filed; no new matter is added.

Rejections Under 35 U.S.C. §102

Claims 1 and 2 have been rejected under 35 U.S.C. §102(b) as anticipated by Thim et al., EP 0195691 and Kjeldsen et al., U.S. Patent No. 6,214,547. The Examiner contends that the original claims of the instant application encompassed insulin preparations containing either (i) no glycosylated insulin or (ii) more than 0.2% glycosylated insulin; and that the disclosures of Thim et al. and Kjeldsen et al. of expression of human insulin precursors in yeast thus anticipate the claims.

While Applicants do not agree with the Examiner's construction of the claims, to expedite prosecution the claims have been amended to remove any possible ambiguity allegedly arising from the use of the terms "comprising" and "about". In their current form, the claims encompass insulin preparations containing between 0.02-0.2% glycosylated insulin or insulin analogue (the undesired product) with the remainder (99.8-99.98%) being unglycosylated insulin (the desired product).

The present invention relates to the fact that high-level expression of insulin in yeast results in the production of significant amounts of glycosylated forms of insulin relative to the total insulin produced and the consequent need to produce purified preparations having significantly lower levels of glycosylated insulins.

Neither Thim et al. nor Kjeldsen et al. addresses the issue of glycosylated forms of insulin and neither contains any teaching of separation methods that could produce the presently claimed preparations. Accordingly, it is respectfully submitted that neither citation can anticipate the present claims and that this rejection may be withdrawn.

In view of the above amendments and remarks, it is believed that the claims are in condition for allowance, and a determination to that effect is earnestly solicited.

Respectfully submitted,

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